

REMARKS

I. Claim Amendments

Claims 1, 19 and 27 have been amended to clarify that the expression “analyzing position” is intended to convey the place or location within the claimed apparatus at which the sample is analyzed and subjected to an optical measurement. Support is provided by the entirety of the specification, e.g., at page 8, lines 22-30, and at page 9, lines 15-16. No new matter has been added.

II. Allowable Subject Matter

Applicants are appreciative of the indication that claims 3, 8-11, 16, 22 and 23 represent allowable subject matter. However, for the reasons set forth below, Applicants respectfully submit that all pending claims 1-3, 6-23 and 25-28 are in condition for allowance.

III. Claim Rejections – 35 U.S.C. §112

Claims 1-3, 6-23 and 25-28 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The recited expression “analyzing position”, as contemplated by the claimed invention, does not refer to the first and second holding parts. Rather, as explained in Section I, above, the expression “analyzing position” is intended to convey the place or location where the sample is analyzed and subjected to an optical measurement.

Withdrawal of the §112 rejection is requested.

IV. Claim Rejections – 35 U.S.C. §103

A. US 5,463,223 to Wong et al. (“Wong”)

Claims 1, 2, 6, 17-21, 27 and 28 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Wong. For the following reasons, Applicants submit that Wong neither suggests the claimed invention nor provides the requisite motivation to modify Wong to arrive at the claimed invention.

Apparatus claims 1 and 27 are the only independent claims. As such, all of the dependent apparatus and method claims are either directly or indirectly dependent on claim 1 or 27, whichever the case maybe. The claimed apparatus as defined by independent claims 1 and 27 is defined by the following structural elements which are essential to its structural integrity and operation:

- a) a feeding means for feeding one or more pharmaceutical samples to an analyzing position, and
- b) a fixing means for temporarily fixing the sample at the analyzing position.

At page 3 of the Office Action, the Examiner acknowledges that Wong "does not explicitly describe a feeding means". The Examiner concludes, however, that "it would have been obvious to one of ordinary skill in art to have some means to feed samples to the analyzing position, otherwise the samples would not be able to be analyzed."

Applicants agree that Wong does not disclose or suggest a feeding means. Moreover, contrary to the Examiner's position, modification of Wong to include a feeding means as contemplated by the claimed invention would destroy the intent, purpose and function of that reference. Accordingly, the obviousness rejection based on Wong is improper.

Wong is directed to a sample holder for use in spectroanalysis of a sample. The sample holder is said to be suitable as a single use (col. 3, line 46) and disposable (col. 3, line 47). Additionally, the sample holder is said to require minimal assembly of its component parts (col. 3, lines 50-51): a rigid frame, an optical window and a flexible film (claim 1). In general, Wong discloses two embodiments of the sample holder: a first embodiment represented by Figures 1-6 (col. 5, line 60 to col. 8, line 65) and a second embodiment represented by Figure 7 (col. 8, line 66 to col. 9, line 62).

In accordance with the first embodiment, an optical window 4 is mounted in the upper section 2a of the frame 1 (col. 6, lines 60-61). A flexible film 6 is preferably mounted to the upper surface 1a of the frame 1 so that only one edge of the film 6 is attached by an appropriate means, such as, for example, by the application of a line of an adhesive 7 or by heat fusion (col. 7, lines 5-59). In use, the film 6 is raised up and a sample 25 to be analyzed is placed onto the

optical window 4. The film is then lowered to cover the sample 25 and the bore 2 as shown in Figure 1C. The film is then manually pressed down to contact the sample (col. 8, lines 11-15).

Wong does not expressly state whether the sample holder is first assembled and then the completely assembled sample holder is mounted onto the spectrophotometer, or whether just the frame is first mounted on the spectrophotometer followed by mounting the optical window and film to complete the sample holder (col. 6, lines 37-42). Furthermore, Wong is silent regarding the timing for placing the sample to be analyzed onto the optical window, i.e., before or after the sample holder has been completely assembled and mounted onto the spectrometer. However, Applicants submit that safe, efficient and common sense laboratory practice would dictate assembly of the sample holder and placement of the sample onto the optical window prior to mounting the completely assembled sample holder onto the spectrometer. Nevertheless, it is abundantly clear in view of Figures 1-6 and the relevant disclosure that assembly of the sample holder and placement of the sample to be analyzed onto the optical window are performed manually.

Therefore, with respect to the first embodiment (Figs. 1-6), there is no meaningful suggestion that either assembly of the sample holder or placement of the sample onto/into the sample holder is performed by a structural means that is essential to the structural integrity and operation of the storage holder and spectrometer. In fact, the weight of the disclosure by Wong is strongly suggestive that that these operations, i.e., assembly and placement, are performed manually.

The second embodiment of Wong is illustrated by Figure 7. In this embodiment, two sample holders 11 and 12 are clamped together by two screws 9 and the film 6 is not required (col. 9, lines 1-3). Prior to clamping the upper sample holder 21 onto the lower sample holder 11, the sample 25 is placed onto the optical window 4a of the lower sample holder 11 (col. 9, lines 22-25).

Just as with the first embodiment, the description of the second embodiment (Fig. 7) is silent regarding the sequence for assembling and mounting the storage holder onto the spectrometer. There is also no disclosure regarding the timing for placing the sample to be analyzed onto the optical window, i.e., before or after the sample holder has been completely assembled and mounted onto the spectrometer. However, with the second embodiment, it is

clearer that placement of the sample onto the optical window and assembly of the sample holder must be performed prior to mounting onto the spectrometer. It would seem that restrictions imposed by the actual design and structure of the spectrometer would preclude clamping the upper sample holder, e.g., by the insertion and/or tightening of screws, onto the lower sample holder which was first mounted onto spectrometer to receive the sample. Again, there is a strong suggestion that these operations, i.e., assembly and placement, are performed manually.

For purposes of obviousness, it is not enough that a sample is somehow fed to the analyzing position as stated by the Examiner on page 3 of the Office Action. Rather, the prior art must suggest the claimed invention as defined by its component parts. According to the claimed invention, the feeding means is a structural part of the claimed apparatus and not an extraneous means, e.g., an operator, pipette, spoon, etc., coming from a source other than a structural element of the apparatus. For all of the preceding reasons, neither the first embodiment (Figs. 1-6) nor the second embodiment (Fig. 7) of Wong suggests or requires the recited feeding means of the claimed invention which is integral to the structure and function of the apparatus. In fact, Applicants submit that modification of Wong to include a feeding means that is essential to the structural integrity and operation of the storage holder and spectrometer would defeat the intent, purpose and function of Wong which requires manual steps to assemble the storage holder and to place the sample onto the sample holder, e.g., raising up the film to place the sample onto the optical window, lowering the film to cover the sample and pressing down on the film to contact the sample.

With specific regard to method claims 18-21 and 28, it is important to note that these claims are either directly or indirectly dependent on apparatus claim 1 or 27. Moreover, the method claims expressly recite that the sample is fed to the analyzing position by the feeding means (See claim 18, step (a)). Because the claimed method is dependent upon the operation of the claimed apparatus comprising a feeding means, it is submitted that the claimed method is not obvious in view of Wong for the same reasons that Wong does not suggest a feeding means that is essential to the structural integrity and operation of the storage holder and spectrometer.

Withdrawal of the §103 rejection of claims 1, 2, 6, 17-21, 27 in view of Wong is requested.

B. Wong + US 5,679,954 to Soloman ("Soloman")

Claims 7, 12 and 26 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Wong in combination with Soloman.

The Examiner relies on Soloman for the alleged disclosure of a feeding means comprising a pre-alignment means for receiving and holding a sample during transport to an analyzing position. The Examiner concludes that it would have been obvious to combine the feeding means of Soloman with the apparatus of Wong because it would provide an efficient and automated way to move solid samples in sequence to the analyzing device.

The Federal Circuit has consistently held a *prima facie* case of obviousness cannot be properly made when a §103 rejection is based upon a modification of a reference that destroys the intent, purpose and function of the invention disclosed in the reference. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)

Wong is directed to a sample holder that is suitable as a single use (col. 3, line 46) and disposable (col. 3, line 47) thereby eliminating contamination and disposal problems with cleaning sample holders for reuse (col. 3, lines 44-49). In accordance with Wong, the sample holder is manually assembled for mounting onto a spectrometer to present a sample for spectroanalysis. After the analysis, the sample holder and sample are then discarded and the procedure, i.e., assembly and mounting, is repeated with the next sample. To modify Wong to include the feeding means of Soloman would destroy the intent, purpose and function of Wong which is to use a sample holder that is disposable and suitable as a single use.

For all of the foregoing reasons and the relevant case law, Applicants submit that a *prima facie* case of obviousness has not been established. Withdrawal of the §103 rejection of claims 7, 12 and 26 in view of the combination of Wong and Soloman is requested.

C. Wong, Soloman + DE 44 41 686 ("Schilling")

Claims 13-15 and 25 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the combination of Wong, Soloman and Schilling.

Schilling is cited for the alleged disclosure of an on-line sample receiver which provides a feeder wheel with samples. The Examiner concludes that it would have been obvious to

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combine Wong, Soloman and Schilling because use of a sample receiver would (1) ensure that a constant supply of tablets to be tested are always available and (2) lend itself to in-line sampling.

Schilling does not overcome the deficiencies of Wong and Soloman as discussed in the preceding sections. Specifically, modification of Wong to include the feeding means of Soloman and the sample receiver of Schilling would destroy the intent, purpose and function of Wong which is to use a sample holder that is disposable and suitable as a single use. Furthermore, the single use and disposable nature of Wong is clearly not intended for in-line sampling. In accordance with Wong, the sample holder is manually assembled for mounting onto a spectrometer to present a sample for spectroanalysis. After the procedure, the sample holder and sample are then discarded and the procedure, i.e., assembly and mounting, is repeated with the next sample. No reasonable or permissible interpretation of Wong properly lends itself to a modification of that reference to include the feeding means of Soloman and the sample receiver of Schilling for in-line sampling.

For all of the foregoing reasons and the relevant case law, Applicants submit that a *prima facie* case of obviousness has not been established. Withdrawal of the §103 rejection of claims 13-15 and 25 in view of the combination of Wong, Soloman and Schilling is requested.

CONCLUSION

Applicants submit that claims 1-3, 6-23 and 25-28 are in condition for allowance, which action is earnestly solicited. The Commissioner is hereby authorized to charge Deposit Account No. 23-1703 in the event that any fee is required in connection with this communication.

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Respectfully submitted,



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